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| APPLICATION NO.                                                                                          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/479,548                                                                                               | 01/07/2000  | MATTHIJS P SMITS     | 8668.2029           | 3197             |
| 7590                                                                                                     | 04/08/2004  |                      | EXAMINER            |                  |
| ROBERT M ISACKSON ESQ<br>ORRICK HERRINGTON & SUTCLIFFE LLP<br>666 FIFTH AVENUE<br>NEW YORK, NY 101030001 |             |                      | FAULK, DEVONA E     |                  |
|                                                                                                          |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                                          |             |                      | 2644                | 9                |
| DATE MAILED: 04/08/2004                                                                                  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 09/479,548      | SMITS ET AL. |
|                              | Examiner        | Art Unit     |
|                              | Devona E. Faulk | 2644         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 January 2000.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 28-65 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 28,-33,35,40,42,47,52,53,56,59,64,65 is/are rejected.  
 7) Claim(s) 34,36-39,41,43-46,48-51,54,55,57,58,60-63 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 7,8.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims **28-35,37,42, 47,52,53,56,59, 64 and 65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1,3,6,7,8,33,34-38, 44 and 45** of U.S. Patent No.6,620,100. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identified claims of the application 09/479,548 disclose a device and method for evaluation of hearing loss that have the same functionality as claimed in the identified claims of U.S. Patent No. 6,620,100. Claims 28-35,37,42,47,52,53,56, and 59 are overall broader than the corresponding claims 1,3,6,7,8,33,34-38,44 and 45 and thus it would have been obvious that anything that infringed on the narrower claims of the patent would infringe on the broader claims of pending application.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 2644

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 28,29,31,33,35** are rejected under 35 U.S.C. 102(b) as being anticipated by Thorton et al. (U.S. Patent 4,375,744).

Regarding claims **28,29,31,33 and 35**, Thorton discloses an auditory response detection method and apparatus comprising a stimulus generator (11) that provides a series of pulses to an earphone (12), which reads on “means for repeatedly delivering an auditory stimulus”; a signal sampler (17) that is synchronized with the pulses delivered by the stimulus generator and samples the magnitude of the EEG signal (column 3, lines 57-67), which reads on “means for sampling an EEG response to said stimulus”; a signal conditioner (15) that filters out the signal components above and below the range of frequencies of interest (column 3, lines 10-37, which reads on “means for detecting noise associated with said EEG response”). It is interpreted that the signal components comprise noise components including non-physiological noise and ambient acoustic noise.. A decision is made as to whether the subject is responding by selecting a statistical confidence limit (See abstract), which reads on “automatically determining when said amount is excessive relative to a threshold”.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 40,42,47,52,53,56 and 59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorton et al. (U.S. Patent 4,275,744).

Regarding claims **40,42,47, 52,53,56 and 59**, Thorton discloses an auditory response detection method and apparatus comprising a stimulus generator (11) that provides a series of pulses to an earphone (12), which reads on “means for repeatedly delivering an auditory stimulus”; a signal sampler (17) that is synchronized with the pulses delivered by the stimulus generator and samples the magnitude of the EEG signal (column 3, lines 57-67), which reads on “means for sampling an EEG response to said stimulus”; a signal conditioner (15) that filters out the signal components above and below the range of frequencies of interest (column 3, lines 10-37, which reads on “means for detecting noise associated with said EEG response”. It is interpreted that the signal components comprise noise components including non-physiological noise. A decision is made as to whether the subject is responding by selecting a statistical confidence limit (See abstract), which reads on “determining when said bias is excessive relative to a threshold”. With regards to polarity, Thorton teaches of using polarity bias to determine if a response has been detected. (column 2, lines 13-24). It is obvious that although Thorthon is not using polarity bias to detect noise, that it could be done if he had designed his apparatus to do so. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use polarity bias to detect noise for the benefit of being able to more accurately perform hearing tests.

***Claim Objections***

7. Claims 34,36-39,41,43-46,48-51,54,55,57,58,60-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
  
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to method or device for hearing evaluation:

- U.S. Patent 6,475,163 to Smits et al.
- U.S. Patent 6,343,230 to Smits et al.
- U.S. Patent 5,601,091 to Dolphin

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devona E. Faulk whose telephone number is 703-305-4359. The examiner can normally be reached on 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W. Isen can be reached on 703-305-4386. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MINSUN CHI / MARY  
PRIMARY EXAMINER